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A-2

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/183, 972 10/29/98 HAGEMAN

G UIA-027.01

HM12/0627

EXAMINER

PATENT GROUP  
FOLEY HOAG & ELIOT  
ONE POST OFFICE SQUARE  
BOSTON MA 02109

TURNER, S

ART UNIT

PAPER NUMBER

1647

12

DATE MAILED:

06/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/183,972	Applicant(s) Hageman
Examiner Sharon L. Turner, Ph.D.	Group Art Unit 1647

Responsive to communication(s) filed on 4-10-00

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-32 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-32 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3 and 14-17, drawn to nucleic acids and kit, classified in class 536, subclass 23.1.
  - II. Claims 4-13, drawn to polypeptides, classified in class 530, subclass 300.
  - III. Claims 18-20 and 21, drawn to a method of treating or preventing development of disease with a nucleic acid, classified in class 514, subclass 44.
  - IV. Claims 18-20 and 22, drawn to a method of treating or preventing development of disease with a protein, classified in class 514, subclass 2.
  - V. Claims 23, drawn to a method of identifying agents which bind to protein, classified in class 435, subclass 7.1.
  - VI. Claims 24, drawn to a method of identifying an agent which bind to nucleic acids, classified in class 435, subclass 6.
  - VII. Claim 25, drawn to a method of identifying an agent that modulates gene expression, classified in class 435, subclass 4.
  - VIII. Claim 26-27, drawn to antibodies, classified in class 530, subclass 387.9.
  - IX. Claim 28-29, drawn to a method of establishing a genetic profile, classified in class 435, subclass 6.

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X. Claim 30, drawn to a method of selecting a therapeutic, classified in class 435, subclass 6.

XI. Claims 31-32, drawn to primers, classified in class 536, subclass 24.3.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I, II, VIII and IX are related as products. The products of groups I, II, VIII and IX are distinct each from the other because of their different sequence structure, lengths, encoding capabilities and biological activities, including compositions of nucleic acids, amino acids and immunoglobulins.

4. Groups III-VII and X-XI are related as processes. The processes of groups III-VII and X-XI are different each from the other as they comprise different steps, use different components and perform different functions, including mutually exclusive and independent methods for therapy or prevention of disease. Invention III requires administration of a DNA sufficient to obtain treatment whereas Invention IV requires the administration of a protein to obtain treatment of disease. Invention V is a method of identifying agents which bind exclusively to nucleic acids whereas Invention VI is a method of identifying agents which bind exclusively to proteins. Invention VII is a method for selecting gene expression modulators, Invention IX, a method of establishing genetic profiles and Invention X, a method of selecting therapeutics based on genetic profiles. The effects of the methods concern different applications, reagents and steps.

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5. Inventions I, II, VIII or IX and III-VII or X-XI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes of treatment, identifying compounds, establishing genetic profiles or selecting treatments can be practiced with alternative compounds such as antibodies, organic or inorganic chemicals and alternative nucleic acids. In addition, any of the nucleic acid, protein, antibody or inorganic products could alternatively be used in a process for assaying for inhibitors, generating antibodies or for diagnosing disease.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for each of the groups is not required for any other group, restriction for examination purposes as indicated is proper.

8. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to, Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to

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reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.

June 26, 2000

*Patricia A. Duffy*  
PATRICIA A. DUFFY  
PRIMARY EXAMINER